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EXAMINER	
HANLEY, SUSAN MARIE	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,568	KISHORE ET AL.	
	Examiner	Art Unit	
	SUSAN HANLEY	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 November 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) *40,41,52,56-59,61-67,72-78,81-84 and 98-101* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,15,19-39,103 and 104* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *11 October 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/18/2010*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1-5,15,19-30,32-41,52,56-59,61-67,72-78,81-84,98-101,103 and 104.

DETAILED ACTION

Claims 1-5, 15, 19-30, 32-41, 52, 56-59, 61-67, 72-78, 81-84 and 98-101, 103 and 104 are pending.

Election/Restrictions

Applicant's election with traverse of Group II, claims 2, 15 and 19-29 and the specie poly-D-aspartic acid in the reply filed 11/11/2011 is acknowledged. The traversal is on the ground(s) that on there is no serious burden on the examiner to examine the groups together and that burden has not been demonstrated. This is not found persuasive because the instant application is a national stage entry and the restriction was based on 35 USC 371 in which the determination or restriction is based on lack or unity, or the lack of a common special technical feature which was demonstrated in the restriction requirement. Search burden is not a component for lack of unity. Upon further consideration, the restriction requirement for groups I and III is withdrawn since these compositions are disclosed by the prior art. The specie election is also withdrawn.

The requirement is still deemed proper and is therefore made FINAL.

Claims 40, 41, 52, 56-59, 61-67, 72-78, 81-84 and 98-101 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 11/11/2010.

Claims 1-5, 15, 19-39, 103 and 104 are presented for examination.

Double Patenting

Applicant is advised that should claim 103 be found allowable, claim 104 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

Specification

The specification remains objected to becasue in the Brief Description of the Drawing Figures 21, 22 and 27 have multiple parts and they should be described separately.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 36, 38 and 39 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. A single claim that claims both an product or apparatus and the method steps of using the product or apparatus should be rejected under 35 U.S.C. § 101 based on the theory that the claim is directed to neither a "process" nor a "machine," but rather embraces or overlaps two different statutory classes of invention set forth in 35 U.S.C. § 101, which is drafted so as to set forth the statutory classes of invention in the alternative only. *Ex parte Lyell,*17 USPQ2d 1548

(Bd. Pat. App. & Inter. 1990) at 1551. See M.P.E.P. §2173.05(p). In this case, the parent independent claim 30 is drawn to a composition comprising a cell treated with an EPIP that is capable of producing Ep. Claim 36 is further drawn to a method of administering poly-d-glutamic acid. Claim 38 is further drawn to a method of stimulating the cells and claim 39 is further drawn to a method of treating proximal tubular cells with an EPIP. The claims are interpretable as composition or method claims.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 36-39 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 20 is rejected be cause “the preservative’ lacks antecedent basis in claim 2.

Claim 37 is rejected because the phrase “continues to express erythropoietin" is inconsistent with claim 30 becasue the cells in claim 30 are capable of expressing Ep but it is not claimed that they are expressing Ep in claim 30.

Claims 36, 38 and 39 are rejected becasue they are conflicting. The claims are drawn to both a composition and a method in a single claims as noted supra.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Owen et al. (US 2003/0198452; cited in the restriction requirement mailed 10/13/2010).

Using the instant specification as a dictionary, an EPIP is any peptide that directly or indirectly stimulates the proliferation of fibroblasts which in turn produces Ep (p. 18, lined 8-10). Owen et al. disclose the administration of FLAK peptides to human fibroblasts and the stimulation of the production of fibroblasts by the FLAK peptides (p. 19, Table 22). Hence, the method of Owen et al. produces a composition comprising cells containing a peptide that stimulates the production of a fibroblast (an EPIP) which in turn makes Ep. Hence, a composition of cells comprising Ep and an EPIP is disclosed (instant claim 1).

This is a rejection of the generic claim.

Claims 2, 4, 15, 19 and 29 are rejected under 35 U.S.C. 102(e) as being anticipated by Mekalanos et al. (US 20030108556).

Mekalanos et al. disclose a composition of 3 mg or the “D” isomer of polyglutamic acid dissolved in 5 ml of water, meeting the limitations of instant claims 1 and 15 since poly-D-glutamic acid is named (section [0135]). The limitations of instant claim 4 are

met since even a miniscule amount of the poly-D amino acid will have a therapeutic effect. The limitations of claim 19 are met since water is a carrier. The solution is aqueous (instant claim 26). Since the composition is a solution, it is injectable (instant claim 29).

The reference is silent regarding the EPIP-inducing characteristics of the poly-D-glutamic acid, but meet the claimed limitations since the polymer is disclosed, which indicates that the claimed characteristics should be present in the prior art invention as also as those instantly claimed. In this case, burden is shifted to the Applicant to distinguish the instant invention over the prior art.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe naturally includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

Claims 1-5, 19, 21, 23, 24, 26, 29, 30, 33-35, 37-39, 103 and 104 are rejected under 35 U.S.C. 102(b) as being anticipated by Fewell et al. (WO 01/66149; cited in the IDS filed 4/20/2006) in view of evidence from Sigma Catalog (1998).

Fewell et al. disclose a pharmaceutical composition comprising a nucleic acid and an anionic polymer that is poly-D-glutamic acid, poly-L-aspartic acid, poly-L-glutamic acid, poly-D-aspartic acid or polyacrylic acid or polyvinyl sulfate (abstract). A

vector (an Ep gene inserted into CMV; Ep is called EPO by Fewell et al.) was formulated with poly-L-glutamate and administered to animals by intramuscular injection. The DNA/poly-L-glutamate was formulated in saline (p. 33, lines 20-24). Ep was expressed in the cells (Example IV, p. 55-57). The ordinary artisan would reasonably conclude that the some of the poly-L-glutamate would be in equilibrium with the acid since it is in solution. Furthermore, it is noted that the solutions of the poly-D-glutamic acid of the instant application are formed in the same manner. The instant specification discloses at p. 62 that the poly-D-glutamic acid was supplied by Sigma. Sigma Catalog teaches that poly-D-glutamic acid is supplied as the sodium salt (p. 2105).

Thus, the ordinary artisan would reasonably conclude that the cells comprise poly-L-glutamic acid and the cells are capable of expressing Ep due to the presence of the Ep-encoding vector. This disclosure meets the limitation of a composition comprising Ep and EPIP (instant claims 1, 103 and 104) since the treatment of the cells results in a composition (cells) that contain poly-L-glutamic and the Ep thus produced.

Fewell et al. are silent regarding the EPIP-inducing characteristics of the poly-L-glutamic acid, but meet the claimed limitations since the polymer is disclosed, which indicates that the claimed characteristics should be present in the prior art invention as also as those instantly claimed. In this case, burden is shifted to the Applicant to distinguish the instant invention over the prior art.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which

there is reason to believe naturally includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

The limitations of claim 30 are met since a cell is treated with an EPIP and a nucleic acid that is capable of expressing Ep. Regarding the preamble of instant claim 30, it is drawn to how the claimed cell is made. The recitation has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). In the instant case, the body of the claim is drawn to a cell comprising an EPIP. The preamble does not result in a structural difference to what is claim in the body of the claim which a cell treated with an EPIP that is capable of expressing Ep.

Even if the preamble was given patentable weight, it is a recitation of a product by process, the M.P.E.P. § 2113 reads, "Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps."

"Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-

process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe,* 777 F.2d 695, 698,227 USPQ 964,966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Gamero,* 412 F.2d 276, 279, 162 USPQ 221,223 (CCPA 1979).

In the instant case, the patentability is based on the product itself which is a cell treated with one of the poly-L polymer (EPIP) and a nucleic acid that expresses Ep. The method steps expressed in the instant preamble do not exclusively define the product.

The Ep expressed is an equivalent to that from a recombinant source since the structures of the proteins produced naturally and recombinantly are the same (instant claim 5). The EPIP and Ep are in a therapeutically effective amount since even a miniscule amount of each has an effect on a cell an would ameliorate the symptoms of a disease albeit in a small degree (instant claims 3 and 4).

Fewell et al. are silent regarding the EPIP-inducing characteristics of the poly-L polymer, but meet the claimed limitations since the poly-L polymer is disclosed, which indicates that the claimed characteristics should be present in the prior art invention as also as those instantly claimed. Regarding the amount of Ep produced (instant claims

33-35), the rate of Ep production (instant claim 33) or if the cells continue to express Ep after exposure to the poly-L-glutamic acid (instant claim 37), the cells contain a mechanism to make Ep (the administered DNA). In this case, burden is shifted to the Applicant to distinguish the instant invention over the prior art.

It is noted that In re Best (195 USPQ 430) and In re Fitzgerald (205 USPQ 594) discuss the support of rejections wherein the prior art discloses subject matter which there is reason to believe naturally includes functions that are newly cited or is identical to a product instantly claimed. In such a situation the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on" (205 USPQ 594, second column, first full paragraph).

The limitations of claim 2 are met since a composition comprising poly-L-glutamic is disclosed. The limitations regarding a therapeutically effective amount (instant claim 4) are met since even a miniscule amount will have a therapeutic effect albeit to a small degree. The composition is in injectable form (instant claim 29). The DNA/poly-L-glutamic acid was formulated in saline or Tris at pH 7.5 (p. 33, lines 20-24). The disclosure of formulation in saline meets the limitations of a carrier (instant claim 19), an isotonicity adjusting agent (NaCl; instant claim 23) and an aqueous solution (instant claim 26). The disclosure of Tris meets the limitations of a buffer (instant claim 21). The limitations of claim 24 are met since a buffer is a pH adjusting agent and Tris buffers at 7.5 which is a specie of the claimed pH range of 5 to 8.

Claims 38 and 39 are interpretable as composition claims. The limitations of these claims are met since the composition is disclosed supra.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-5, 15, 19, 21, 23, 24, 26, 27, 29, 30, 32-36, 37-39, 103 and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fewell et al. (WO 01/66149; cited in the IDS filed 4/20/2006) in view of evidence from Sigma Catalog (1998).

The rejection of instant claims 1-5, 19, 21, 23, 24, 26, 29, 30, 33-35, 37-39, 103 and 104 is discussed supra.

Fewell et al do not teach that the polyanionic polymer is poly-D-glutamic acid (instant claims 15, 32 and 36, wherein claim 36 is interpreted as a composition claim),

or that the vector comprising a nucleic acid encoding EP and the polyanionic polymer specifically formulated for oral administration (instant claim 27).

As noted, Fewell et al. disclose that the poly-D-glutamic acid is a functional equivalent of poly-L-glutamic acid as a transfection agent for nucleic acids (abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ poly-D-glutamic acid as the polyanionic polymer in the nucleic acid formulation taught by Fewell et al. The ordinary artisan would have been motivated to do so because each polyanionic polymer is known to have the same function, transfecting DNA into cells. Hence, the substitution is no more than the predictable use of prior art elements according to their established functions resulting in the simple substitution of one known element for another for a predictable result. The ordinary artisan would have had a reasonable expectation that one could successfully employ poly-D-glutamic acid since Fewell et al. indentify it as a functional equivalent to poly-L-glutamic acid.

Fewell et al. teach that alternative forms of the formulation are topical, oral, pulmonary, nasal, mucosal, buccal, vaginal or rectal which is a small genus of eight members (p. 25, lines 16-20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to administer the disclosed formulation in an oral form. The ordinary artisan would have been motivated to do so becasue Fewell et al. suggest it and the selection or an oral dosage form is easily envisage by the ordinary artisan from a small genus of eight members. The ordinary artisan would have had a reasoanble

expectation that one could formulate the disclosed mixture orally since Fewell et al. suggest this.

Claims 1-5, 19, 21, 23, 24, 26, 28, 29, 30, 33-35, 37-39, 103 and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fewell et al. (WO 01/66149; cited in the IDS filed 4/20/2006) in view of evidence from Sigma Catalog (1998) in view of Maskiewicz et al. (US 2001/0038859).

The rejection of instant claims 1-5, 19, 21, 23, 24, 26, 29, 30, 33-35, 37-39, 103 and 104 is discussed supra.

Fewell et al do not teach that the disclosed DNA/poly-amino polymer composition is formulated with a surfactant wherein the components are mixed in liquid phase and lyophilized (instant claim 28). The ordinary artisan would reasonably conclude that the final from of the formulation would be a dry solid such as a powder due to the lyophilization process.

Maskiewicz et al. disclose formulations for pharmaceutical composition comprising proteins or DNA wherein the compositions remain is a dry stable powder from until used for administration via injection, etc. (abstract). Maskiewicz et al. teach that the powders can be produced by lyophilization and that they may include surfactants which protect from surface absorption and solubilize the protein or nucleic acid (section [0096]).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the DNA/poly-amino polymer composition of Fewell et

al. as a dry powder that comprises a surfactant. The ordinary artisan would have been motivated to do so becasue the formation is stable until need for administration. The ordinary artisan would have had a reasoanble expectation that one could formulate the composition of Fewell et al. in a surfactant as a powder since the composition of Fewell et al. comprises DNA and a protein which is what Maskiewicz seek to formulate.

It is noted that claim 28 recites that the composition is mixed in a liquid phase and then lyophilized. As noted, the ordinary artisan would reasonably conclude that the result of this process would yield a dry solid that can be a powder. Thus, the recitation is a product by process and the combined disclosure meets the limitations of instant claim 28 since a dry solid comprising a surfactant, DNA and a poly-amino polymer is disclosed. As noted supra, in a product-by -process claim, the patentability of the product rests with the product.

Claims 1-5, 19, 21-26, 29, 30, 33-35, 37-39, 103 and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fewell et al. (WO 01/66149; cited in the IDS filed 4/20/2006) in view of evidence from Sigma Catalog (1998) in view of Sims et al. (US 6,080,557).

The rejection of instant claims 1-5, 19, 21, 23, 24, 26, 29, 30, 33-35, 37-39, 103 and 104 is discussed supra.

Fewell et al do not teach that the disclosed DNA/poly-amino polymer composition is formulated with a buffer that is phosphate or with human serum albumin (HSA; instant claims 22 and 25, respectively).

Sims et al., teach that representative carriers for injectable solutions of composition for gene therapy include isotonic saline which are preferably buffered at a physiological pH with phosphate buffered saline or Tris-buffered saline. A particularly preferred formation includes mannitol, HSA, Tris and NaCl (col. 22, line 34 to col. 23, line 15).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to formulate the injectable solution of DNA and the poly-amino polymer composition in saline buffered Tris buffer with HSA and mannitol. The ordinary artisan would have been motivated to do so becasue Sims et al. particularly recommends this formulation for vector formulations for gene therapy. The ordinary artisan would have been motivated to employ phosphate buffered saline for the Tris buffered saline becasue Sims et al. names them as functional equivalents for buffering purposed. The ordinary artisan would have had a reasoanble expectation that one could formulate the DNA/poly-amino polymer composition with phosphate buffer saline, mannitol and HSA since Sims teach that such a formulation is appropriate for gene therapy.

Claims 1-5, 19-21, 23, 24, 26, 29, 30, 33-35, 37-39, 103 and 104 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fewell et al. (WO 01/66149; cited in the IDS filed 4/20/2006) in view of evidence from Sigma Catalog (1998) in view of Ding et al. (US 2003/0219407).

The rejection of instant claims 1-5, 19, 21, 23, 24, 26, 29, 30, 33-35, 37-39, 103 and 104 is discussed supra.

Fewell et al. do not teach that the DNA/poly-amino polymer composition includes a preservative such as phenol (instant claim 20).

Ding et al. disclose that it is desirable to formulate composition for gene therapy with a preservative such as phenol in order to prevent the growth of microorganisms in the formulation (section 0118).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to include a preservative in the DNA/poly-amino polymer composition disclosed by Fewell et al. The ordinary artisan would have been motivated to do so becasue the inclusion of a preservative would prevent the growth of microorganism. the ordinary artisan would have had a reasonable expectation that a preservative in the composition disclosed by Fewell et al. would prevent the growth of microorganism since Ding et al. teach this.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SUSAN HANLEY whose telephone number is (571)272-2508. The examiner can normally be reached on M-F 9:00-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Susan Hanley/
Examiner, Art Unit 1651